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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/760,197 | 01/12/2001 | Pedro Aloise | BIO76701 | 2671 |

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John Russell Uren, P. Eng.
Suite 202
1590 Bellevue Avenue
West Vancouver, BC V7V 1A7
CANADA

| EXAMINER | |
|---|---|
| SAYALA, CHHAYA D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1761 | 5 |

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

5a

| Office Action Summary | Application No. 09/760,197 | Applicant(s) Aloise et al |
|---|---|---|
| | Examiner Sayala | Group Art Unit 1761 |

*—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—*

**P riod for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

**Di position of Claims**

☒ Claim(s) 1 - 15 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 - 15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

**Application Papers**

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119 (a)-(d)**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

**Attachment(s)**

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Pat nt Application, PTO-152

☐ Notice of Draftsperson's Pat nt Drawing Review, PTO-948

☐ Other _____

**Office Action Summary**

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The article "A" should be inserted before "method" in each of the claims 1 -14. In claims 12, line 3, "other" is indefinite because, it is not clear what else is included by this language.

In claim 15, even though this claim encompasses more than 40 products, the article ---A--- should be inserted before "product". Claim 15 is improper and indefinite in that it is unclear which method and which claim is being referred to since a number of the claims 1-14 encompass several Markush groups.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/34498 and Stone et.al. (J. Sci. Food Agric. Vol 35, pp 53 -519, 1984) in view of EP 0321004 and Nielsen et al. (US Patent 5989600).

'498 teaches mixing krill hydrolysate with soy, canola and other plant protein along with wheat bran, being brought to a desired temperature of about 45°C, and holding it for about 1 hour at this temperature. The phytic acid and levels of acid and base are measured. Wheat bran is used to provide phytase. The patent teaches that the blend can be maintained to an extended period of time, 4 hours or even longer. The krill hydrolysate product is evaporated and then mixed with and co-dried with a dry carrier, such as canola meal, oil seed meal, which renders obvious the soybean meal and other vegetable meals. The advantages are given at p. 20; see page 19 and page 22, lines 5-10.

'498 also teaches using formic acid to stabilize the hydrolyzed marine protein. It does not teach adding acid to stabilize hydrolyzed feed materials from vegetable/oil seed protein.

However, it would have been obvious to use the same acid to stabilize such since the krill hydrolysate used is the same.

The patent does not teach the use of a phytase enzyme instead of wheat bran, and does not teach the use of a pH between 5 - 5.5.

Stone et. al teach acid-stabilized blend of fish silage, wheat bran and canola meal to make a feed-stuff. The pH is maintained at 4.0 and the final blend is dried. [1].

The use of phytase enzyme is not taught and neither is the pH the same as claimed herein.

EP 0321004 teaches the uses of phytase either from wheat or from microbial source. It also teaches using a combination of enzymes that possess plant degrading properties. See claims 1- 4. See claim 6, wherein the process teaches drying the hydrolyzed product.

Nielsen et al. also teach using a combination of enzymes such as phytase and proteolytic enzymes.[2] The pH is between 4 - 7. The temperatures are from 35 - 650 C. See col. 3, lines 10 - 25.

It would have been obvious to combine krill hydrolyzate, canola meal, phytase or other ~~other~~ film-degrading enzymes used in EP '004 or Nielsen et. al., to prepare a feedstuff as taught by WO '498 and drying the hydrolyzed product as shown in the secondary reference and co-drying with other feed ingredients as shown by

'498. Note that all patents are drawn to hydrolyzing feed materials to make animal feedstuff by using phytase enzyme. To substitute the wheat bran of the primary references (Stone et.al, WO '498) with phytase would have been an obvious substitution since these references teach that wheat bran is used as a phytase source and both Nielsen et. al. and EP'498 use the phytase enzyme itself. The temperatures shown by these references are close to or encompass these parameters claimed herein and to optimize such, based on the known phytase activity around pH 5 to 5.5 would have been an obvious expedient.

6. Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO98/34498, or Stone et.al., or EP 0286056, or Vanderbeke et. al. (US Patent 5554399) or Nielsen et. al (US Patent 5989600) or WO 00/10404 or EP 0321004.

The patents/references above teach the addition of enzymes such as phytase to hydrolyze the same feed materials as claimed herein. ~~of such compounds~~. The flavors are in amounts 0-5% (see claim 1). The rejection is being made under both statutes because the Office is not equipped to make prior art products and compare them with those of applicant's claims and so the burden is being shifted to applicant to show that these product claims are distinguishable over prior art. Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that need be established and not

that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976). When the prior art discloses a product that reasonably appears to be either identical with or only slightly different than the product claimed in this product-by-process claim, the burden is on the applicant to present evidence from which the Examiner could reasonably conclude that the claimed product differs in kind from those of prior art. In re Brown, 459 F2d 531, 173 USPQ 685 (CCPA 1972); In re Fessman, 489 F2d 742, 180 USPQ 323 and 324 (CCPA 1974); In re Marosi, 710 F2d 799, 218 USPQ 195 (Fed Cir. 1983).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication should be directed to Examiner **C. Sayala** at **Group 1761**, telephone number (703) 308-3035. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661. The fax phone number for this Group is (703)305-7718.

C. Sayala
Primary Examiner
Group 1761.